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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,579	12/20/2000	Vahid Saadat	VAA-004	1598
1473	7590	06/04/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			IZAGUIRRE, ISMAEL	
			ART UNIT	PAPER NUMBER
			3765	15

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/746,579	Applicant(s) SAADAT, VAHID
	Examiner Ismael Izaguirre	Art Unit 3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14, 18-22, 24-46 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20, 21 and 55-65 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 18, 19, 22, 24-32 and 35-46 is/are rejected.
- 7) ☐ Claim(s) 5-7, 14, 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIMS

Summary

Claims 1,18,20,22,35,41,55 and 60 are the independent claims under consideration in this Office Action.

Claims 2-8,14,19,21,24-34,36-40,42-46,56-59 and 61-65 are the dependent claims under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to the claim, line 3, the words "during wound healing" have no clear antecedent basis and are confusing. It is unclear if "during wound healing" is intended to be a further method step.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brooks (4,632,097).

Brooks teaches a device including the following structure: a first elongated substrate 31a (figure 1, for example) including first and second surfaces. A second elongated substrate 14 including first and second surfaces. The second surfaces are configured to mate with each other via pulleys 17 and 18 and belt 27. Further, the first surfaces of each substrate are covered by a multiplicity of projecting barbs 252 (figure 6, for example). The words "for adhering to the wound" is considered intended use language and has no critical bearing on the anticipated structural make-up of the apparatus as claimed.

Claims 1-4 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Liu (5,081,714).

Liu teaches a device including the following structure: a first elongated substrate 1 (figure 1, for example) including first and second surfaces. A second elongated substrate 1' including first and second surfaces. The second surfaces are configured to mate with each other. Further, the first surfaces of each substrate are covered by a multiplicity of projecting barbs 12 (the hooks of "hook and loop locking system). The two substrates 1 and 1' are taught as identical and further include perforations with sutures therein (sewing threads 11) for connecting or "tying together" the two substrates. ("Suturing" is defined as the act of joining together by or as by sewing in

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Webster's New World Dictionary-Third Edition). The words "for adhering to the wound" is considered intended use language and has no critical bearing on the anticipated structural make-up of the apparatus as claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22 and 26-32 are rejected under 35 U.S.C. § 102(a or e) as being anticipated by Jacobs et al. (6,645,226).

Jacobs et al. teach an apparatus comprising a biocompatible substrate 1215 (figure 12a, for example) including first and second surfaces. An embodiment is taught where the first and second surfaces are covered by a multiplicity of projecting barbs 308, 309 (figure 3E, for example) which can further include multiple tissue penetrating portions 300 and 302 at the end of the shanks (figures 3A, 3B). The substrate is taught

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as further including perforations 1218 (figure 12B) defining suture eyelets. Jacobs et al. teach tube structure including barbs on the interior or on the exterior of the tubes (figures 10A (illustrating a stent-like substrate) and 11D, for example). The tubes are placed within the wound or about the wound and the tissue is pressed onto the barbs for connection thereto (from column 6, line 44). The substrate is formed of a material, which has, for example been used safely in suture materials and drug delivery devices (column 4, line 63).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18,19,25,35,37-41 and 43-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al. (6,645,226) and further in view of Williams (6,645,226).

Jacobs et al. disclose the invention substantially as claimed. Jacobs et al. teach an apparatus comprising a biocompatible substrate 1215 (figure 12a, for example) including first and second surfaces. An embodiment is taught where the first and second surfaces are covered by a multiplicity of projecting barbs 308, 309 (figure 3E, for example) which can further include multiple tissue penetrating portions 300 and 302 at

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the end of the shanks (figures 3A, 3B). The substrate is taught as further including perforations 1218 (figure 12B) defining suture eyelets. Jacobs et al. teach tube structure including barbs on the interior or on the exterior of the tubes (figures 10A (illustrating a stent-like substrate) and 11D, for example). The tubes are placed within the wound or about the wound and the tissue is pressed onto the barbs for connection thereto (from column 6, line 44). The substrate is formed of a material, which has, for example been used safely in suture materials and drug delivery devices (column 4, line 63). However, Jacobs et al. do not suggest providing a therapeutic agent, and more specifically, impregnating the apparatus with the therapeutic agent.

Williams teaches a biocompatible device for attachment within a body and including first and second surfaces with barbs protruding from a first surface and further includes the use of a therapeutic agent. Williams teaches impregnating the device with a therapeutic agent to provide localized drug delivery (from column 4, lines 4-6).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the substrate of Jacobs et al. as including the use of a therapeutic agent and specifically impregnating the substrate with a therapeutic agent. Providing such an agent would allow the localized treatment of the wound and promote healing.

Claims 24,35,36,41 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al. and further in view of Wholey (5,383,897).

Jacobs et al. disclose the invention substantially as claimed. Jacobs et al. teach an apparatus comprising a biocompatible substrate 1215 (figure 12a, for example)

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including first and second surfaces. An embodiment is taught where the first and second surfaces are covered by a multiplicity of projecting barbs 308, 309 (figure 3E, for example) which can further include multiple tissue penetrating portions 300 and 302 at the end of the shanks (figures 3A, 3B). The substrate is taught as further including perforations 1218 (figure 12B) defining suture eyelets. Jacobs et al. teach tube structure including barbs on the interior or on the exterior of the tubes (figures 10A (illustrating a stent-like substrate) and 11D, for example). The tubes are placed within the wound or about the wound and the tissue is pressed onto the barbs for connection thereto (from column 6, line 44). The substrate is formed of a material, which has, for example been used safely in suture materials and drug delivery devices (column 4, line 63). However, Jacobs et al. do not suggest providing a therapeutic agent, and more specifically, coating the apparatus with the therapeutic agent.

Wholey teaches a substrate for attachment within a body and including first and second surfaces with barbs protruding from a first surface and further includes the use of a therapeutic agent. Wholey teaches coating the device with a therapeutic agent to promote thrombogenesis at the puncture site (from column 4, lines 4-10).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the substrate of Jacobs et al. as including the use of a therapeutic agent and specifically coating the substrate with a therapeutic agent. Providing such an agent would allow the localized treatment of the wound and reduce the post-procedure bleeding time of the patient.

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ALLOWABLE SUBJECT MATTER

Claims 20,21 and 55-65 are allowable over the prior art of record.

Claims 5-7,14, 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

INQUIRIES

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0861.

Any inquiry concerning this communication or earlier communications directed to the examiner should be directed to Mr. Ismael Izaguirre at (703) 308-0892 located in CP2-4B18, Monday through Friday 9:30am to 6:00pm.

A handwritten signature in black ink, appearing to read 'Ismael Izaguirre', with a stylized flourish extending to the right.

**Ismael Izaguirre
Primary Examiner
Group Art Unit 3765**